



PHILIPS

8. 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this pre-market notification is:

Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810

NOV 13 2009

Contact Person:
Mr. Paul Schrader
Senior Regulatory Affairs Mgr
Tel: 978-659-2404
Fax: 978-659-3610
Email: Paul.Schrader@philips.com

This summary was prepared on April 16, 2007.

2. The name of this device is the Philips HeartStart Telemedicine System. Classification names are as follows:

Classification	Pro Code	Description
870.2300	74 MSX	System, Network and Communication, Physiological Monitors

- The HeartStart Telemedicine Server facilitates transmission of physiological data, waveforms and reports from Philips Defibrillators to a remote server that is located in a facility that is prepared to admit patients being transported by an ambulance.
- The new device is substantially equivalent to the previously cleared Philips HeartStart 12 Lead transfer station.

5. The product has a similar clinical intended use as the legally marketed predicate device. The only difference is that this SW now adds the capability to receive patient vital sign data and physiologic waveforms in addition to 12-lead ECG information obtained from Philips defibrillator monitors.
6. The product utilizes the same basic technology (receipt of XML data format) as the legally marketed predicate device.
7. Verification, validation, and testing activities establish the performance and functionality characteristics of the new device. Testing involved system level tests, integration tests and regression tests from hazard analysis. Pass/Fail criteria were based on the specifications and test results showed substantial equivalence. The results demonstrate that the functionality of the modified 12 lead transfer station meets all performance claims.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Philips Medical Systems
c/o Mr. Paul Schrader
Regulatory Affairs Manager
Cardiac Care Business
3000 Minuteman Road, Mail Stop 220
Andover, MA 01810-1099

NOV 13 2009

Re: K091176
Trade/Device Name: Telemedicine Server/System Model 861441
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Monitors Network and Communication System
Regulatory Class: Class II (two)
Product Code: MSX
Dated: September 17, 2009
Received: September 21, 2009

Dear Mr. Schrader:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

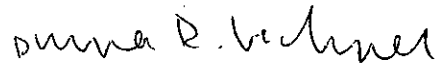
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7. Indications for Use Statement

Page 1 of 1

510(k) Number (if known): K091176

Device Name: HeartStart 12 Lead Transfer Station

Indications for Use:

Intended use of HeartStart Telemedicine Server:

The HeartStart Telemedicine Server software displays patient vitals, waveforms and 12-lead ECG information transmitted from Philips HeartStart defibrillators in remote locations. The HeartStart Telemedicine server allows viewing, diagnostic quality printing, archiving and further distribution of digitized clinical data. The HeartStart Telemedicine Server is also able to forward the 12-lead ECG information into ECG management systems that can process XML format ECG reports such as the TraceMasterVue ECG Management System

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Diana R. Behmer
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091176

Page 15 of 18